

March 28, 2025

**VIA ELECTRONIC FILING**

Hon. Philip M. Halpern  
Southern District of New York  
300 Quarropas St., Courtroom 520  
White Plains, NY 10601

Application granted. The document containing the Guide (Doc. 169) shall remain under seal, and the document containing the placeholder for that exhibit shall remain the publicly-filed version (Doc. 168).

SO ORDERED.



Philip M. Halpern  
United States District Judge

Dated: White Plains, New York  
March 31, 2025

Re: *Regeneron Pharmaceuticals, Inc v. Novartis Pharma AG et al.*, Case No. 7:20-cv-05502-PMH-AEK – Letter Motion to Seal Exhibit to Joint Pre-Motion Letter

Dear Judge Halpern:

Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Defendants Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceutical Corp. (collectively, “Novartis”) are prepared to submit a joint pre-motion letter (“Pre-Motion Letter”) respectfully requesting a conference to resolve a discovery dispute concerning, among other issues, the production of Novartis’s Patent Prosecution Guide (the “Guide”). Among the exhibits attached to the joint letter is a copy of the Guide itself (Regeneron Ex. 2), which was produced by Novartis on an “Outside Counsel’s Eyes Only” basis pursuant to the Stipulated Amended Protective Order (ECF No. 103). Pursuant to Your Honor’s Individual Rule of Practice 5(B), the Standing Order for Electronic Filing Under Seal in Civil and Miscellaneous Cases (1:19-mc-00583), and ECF Rules & Instructions, Regeneron and Novartis write to request permission to file the Guide under seal for the reasons set forth by Novartis below.<sup>1</sup> Novartis has conferred with counsel for Regeneron, and Defendant Vetter Pharma International GmbH, and neither party opposes filing the Guide under seal.

<sup>1</sup> Consistent with the Court’s Individual Rule of Practice 5(B), the parties have contemporaneously filed under seal an unredacted copy of the Guide. Please note, Novartis is seeking to file the Guide under seal in its entirety. While there are highlights in the exhibit, these highlights do not represent Novartis’s proposed redactions, but rather were applied by Regeneron.

Under *Lugosch v. Pyramid Co. of Onondaga*, courts weigh the “common law presumption of access” to judicial documents against “countervailing factors” like the privacy interests of the parties. 435 F.3d 110, 119–20 (2d Cir. 2006). Notably, “[t]he presumption of public access in filings submitted in connection with discovery disputes or motions *in limine* is generally somewhat lower than the presumption applied to material introduced at trial, or in connection with dispositive motions such as motions for dismissal or summary judgment.” *Fairstein v. Netflix Inc.*, 2024 U.S. Dist. LEXIS 93867, at \*3 (S.D.N.Y. May 21, 2024) (quoting *Brown v. Maxwell*, 929 F.3d 41, 50 (2d Cir. 2019)). Any presumption of public access can be rebutted, for instance, by the interest in protecting a company’s business secrets, or where the public disclosure of a company’s confidential business information has the potential to cause competitive injury. See *Lexington Furniture Indus., Inc. v. Lexington Co., AB*, 2021 U.S. Dist. LEXIS 55907, at \*5–6 (S.D.N.Y. Mar. 24, 2021) (“[A] valid need to protect the confidentiality of such sensitive business information may be a legitimate basis to rebut the public’s presumption of access to judicial documents.”); *Sam Dyer & Smr Dyer Farms LLC, v. Agri-Mark, Inc.*, 2022 U.S. Dist. LEXIS 13838, at \*6 (N.D.N.Y. Jan. 21, 2022) (“[C]onfidential business internal policies and procedures are appropriately sealed because the public disclosure of such policies has the potential to cause competitive injury.”).

As the Guide is being filed in relation to a discovery dispute, the public interest in access to this document is “lower” (*Fairstein*, 2024 U.S. Dist. LEXIS 93867, at \*3) and any interest in public access is outweighed by Novartis’s interest in protecting its confidential business information. The Guide was prepared by Novartis’s Patent Prosecution Practice and Pharma Patent Prosecution Efficiency Champions Teams as an internal tool for Novartis’s Intellectual Property Practice Group. See Novartis Ex. A to the Pre-Motion Letter ¶¶ 1–2. It contains the proprietary guidance of Novartis’s intellectual property professionals regarding cost-saving

strategies in patent prosecution, approaches to assessing the commercial relevance of Novartis patents, unique record keeping processes, and other confidential business information. Such sensitive business information is appropriately sealed. *See Kidd v. Thomson Reuters Corp.*, 299 F. Supp. 3d 400, 408 (S.D.N.Y. 2017) (maintaining under seal “proprietary, confidential, and commercially sensitive internal training materials” (citation omitted)). Indeed, the Guide should not be publicized to Novartis’s competitors, who may use it as a tool to their own advantage. *United States v. Amodeo*, 71 F.3d 1044, 1051 (2d Cir. 1995) (“Commercial competitors seeking an advantage over rivals need not be indulged in the name of monitoring the courts . . . .”); *Encyclopedia Brown Prods., Ltd. v. Home Box Off.*, 26 F. Supp. 2d 606, 614 (S.D.N.Y. 1998) (“Confidential business information dating back even a decade or more may provide valuable insights into a company’s current business practices that a competitor would seek to exploit.”).

Moreover, Regeneron argues in the pre-motion letter that Novartis has waived privilege by producing certain unredacted sections of the Guide. While Novartis does not agree that the unredacted sections of the Guide are privileged, to the extent the Court ultimately disagrees with Novartis’s good-faith analysis and determines those sections are privileged, there is an interest in maintaining the Guide under seal to prevent the disclosure of privileged information. *See Novartis Int’l Pharm. AG v. Incyte Corp.*, 2024 U.S. Dist. LEXIS 135547, at \*3 (S.D.N.Y.) (recognizing that the “countervailing interest of preserving the privilege outweighs the presumption of public access” (citing *In re Agent Orange Prod. Liab. Litig.*, 98 F.R.D. 539, 545 (E.D.N.Y. 1983) (“Where unsealing of documents might reveal material governed by the work product privilege or the contents of communications between an attorney and client might be disclosed, the public interest in protecting those privileges would take precedence over its interest in inspecting and copying court records.”))).

For the reasons set forth above, Novartis respectfully requests that the Court grant its unopposed motion to seal and allow Novartis and Regeneron to file Exhibit 2 to the joint pre-motion letter under seal.

Respectfully submitted,

/s/ Christopher M. Pepe

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